Exhibit 8

DEA Compliance Manual

DEA
COMPLIANCE MANUAL

TABLE OF CONTENTS

RECORDS AND REPORTS

PHYSICAL AND PROCEDURAL SECURITY

PREFACE

The Drug Enforcement Administration (DEA) is the primary federal law enforcement agency charged with combating drug abuse in this country. Established in 1973, it is a combination of the agencies formerly known as the Bureau of Narcotics and Dangerous Drugs, the Office for Drug Abuse Law Enforcement, the Office of National Narcotic Intelligence, and certain drug related elements of both the Bureau of Customs and the Office of Science and Technology. The intent of the amalgamation of agencies is to eliminate the piecemeal approach to the control of narcotics and dangerous drugs and, by coordinating the effort, to control more effectively narcotic and dangerous drug activity and abuse.

Prior to this amalgamation of agencies, the laws on the control of drugs were collected and conformed into one piece of legislation, the Comprehensive Drug Abuse Prevention Control Act of 1970 (the "Controlled Substances Act"). This act consolidated over 50 pieces of legislation that had been enacted in piecemeal fashion since 1914. The thrust of this Controlled Substances Act is the improvement of the administration and regulation of manufacturing, distribution, and dispensing of controlled substances by establishing a "closed" system for legitimate drug handlers so that controlled drugs can be traced from their origin to their eventual user.

The act contains nine major control mechanisms that apply to the manufacture, purchase and distribution of substances subject to the act. They are:

- registration of handlers;
- recordkeeping requirements;
- manufacturing quotas;
- distribution restriction;
- dispensing restrictions;
- limitations on imports and exports;
- conditions of storage of drugs;
- reports of transactions to the government; and
- criminal, civil and administrative penalties for violations.

Each of these mechanisms has a considerable impact upon the industry, especially the penalties and loss of registration provisions. Each violation of the act (which may be as little as misplacing one bottle of controlled substances) is punishable by up to 15 years imprisonment and $10,000 in fines. In addition, a relatively speedy administrative hearing can result in a finding of inadequate security. Such a finding could lead to loss of registration, effectively putting a company out of the controlled drugs distribution business. It has, therefore, become a cost justified good business practice to establish effective control measures in the first instance. DEA, like most other federal agencies, prefers voluntary rather than forced compliance.

This manual is intended as a resource to the Controlled Substances Act and Regulations. It is intended as a guide so that you can better understand DEA's function. Further, it is intended to help you learn to deal with the agency that has a tremendous impact on our business.

In addition to this manual, you should also have the following DEA publications available for ready reference:

Code of Federal Regulations 21. Food and Drugs
Part 1300 to End -- *available from:*

Superintendent of Documents
U.S. Government Printing Office
Washington, D.C. 20402
(202) 783-3238

ARCOS Reporting Manual -- *available from:*

United States Department of Justice
Drug Enforcement Administration
ARCOS Unit, P.O. Box 27273
Central Station
Washington, D.C. 20038-7273
(202) 307-8600

Note: The Automation of Reports and Consolidated Orders System (ARCOS) is the automated system developed by DEA to monitor selected controlled substances. ARCOS software enables the government to maintain a current and historical record of controlled substance inventories and transactions from the point of manufacture to the point of sale, distribution, or other disposition, and finally, to the dispensing (consumption) level.

INTRODUCTION

The Controlled Substances Act and implementing regulations (21 CFR 1300 to the end) impose a substantial number of requirements upon wholesalers and other handlers and prescribers of controlled drugs. This training manual deals with the records of controlled drug transactions that must be kept by wholesalers and the reports that wholesalers must submit. The theory behind the records requirements for Schedule III through V controlled drugs is that a registrant's regular, normal business records are acceptable **provided** that they contain all necessary elements of information and that these elements are readily retrievable from the records (more later on retrievability). Special, separate records are required from Schedule II controlled drugs (see Biennial Inventory and Order Forms). The importance of accuracy in taking required inventories and in recording controlled substances transactions should be stressed to wholesaler employees charged with these responsibilities.

INVENTORY

There are specific regulations with regards to inventory. DEA requires a biennial inventory, and a year-end ARCOS inventory. As company policy, periodic inventories are recommended. Unless otherwise specified, the general requirements pertain to each type of inventory.

Biennial

(21 CFR 1304.11 (c))

Frequency. Every two years, the wholesaler is required to take a physical inventory of all controlled drug stocks on hand in live, morgue and brokerage.

When. The regular biennial inventory date is every two years from the date the wholesaler initially became registered to distribute controlled substances. Thus, for all firms who were provisionally registered on May 1, 1971, the biennial inventory date is May 1st every odd year. For any firm registered after May 1, 1971, or which has been issued a new registration since May 1, 1971, the regular inventory date is two years from the initial date of registration, e.g., Firm A which first became registered on August 21, 1974, has a regular biennial inventory date of August 21 every even year. The wholesaler may take the inventory within four days of the inventory date if he/she notifies the DEA special agent in charge in advance.

Changing Inventory Date. To coincide with a fiscal year, year-end ARCOS inventory, general inventory time, or any other reason, the wholesaler may change the controlled drug inventory date to another fixed date provided that the new is within two years of the previous biennial date. DEA does not have to be notified.

Cardinal Health had received prior authorization from DEA for all Cardinal Health locations to conduct biennial inventories on December 31 of even numbered years and will continue to do so. Refer to DEA correspondence 11/21/96.

Year-End ARCOS

(21 CFR 1304.33 (b))

Frequency. Every year, the wholesaler is required to take a physical inventory of all reportable controlled substances on hand in live, morgue and brokerage.

When. The inventory should report the stock on hand as of the close of business on December 31st.

Reporting. A report of the inventory shall be filed with the ARCOS Unit of the DEA by January 15th of the following year.

Periodic
(21 CFR 1304.11, 21 CFR 1301.74)

Frequency. A daily count of controlled substances and narcotics having movement (sales, purchases, and returns) on the previous day should be conducted, and a monthly count of all controlled substances in the facility.

When. Counts should be conducted as close to the end of day processing so as not to interfere with the current day's business. The monthly count should be conducted as close to the same time each month as possible.

General Requirements
Newly Controlled Drugs. An initial inventory must be taken of all stocks on hand of a newly controlled drug on the effective date of control. Subsequently, the newly controlled drug will be reinventoried on the same date as all other controlled drugs. **(21 CFR 1304.11 (d))**

> *Note: Many wholesalers have been cited for missing the initial inventory date on newly controlled drugs. For example, anabolic steroids were controlled (Schedule III) effective February 27, 1991, and an initial inventory should have been taken on that date.*

Drugs to Be Included. All controlled substances on hand as of the inventory date must be included. Returns, damaged goods, and any other drugs awaiting disposal must be inventoried.

> *Note: Wholesalers often overlook returns and drugs awaiting disposal in taking inventory.*

Required Inventory Records. The inventory must be maintained in written, typewritten, or printed form. It should be signed by those taking the count and both the date of the inventory and whether it was taken as of the opening of business or close of business must be recorded. Inventories of all Schedule I (research drugs) and Schedule II substances must be separated from inventories for all other substances. Schedule III through V substances may be maintained separately from all other substances or in a readily retrievable manner. Readily retrievable means that the records (whether ADP, electronic, or mechanical are kept in such a manner that they can be separated out in a reasonable time and/or the items are identifiable visually from other items appearing on the records (asterisk, redlined, etc.).

For each controlled substance in finished form, the required inventories must contain:

- Name of the substance;
- Each finished form (e.g., 10-mg. tablet or 10-mg. concentration per fluid ounce or milliliter;
- Number of units or volume of each finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial); and
- Number of commercial containers of each such finished form (e.g., four 100-tablet bottles or six 3-milliliter vials).

For controlled substance returns, damaged goods, or substances awaiting disposal, the inventory must contain:

- Name of the substance;
- Total quantity of the substance to the nearest metric unit of weight or the total number of units of finished form; and
- Reason for the substance being maintained by the registrant.

(21 CFR 1304.22 (b), 21 CFR 1304.11(2))

Count Requirements. When taking an inventory, the following steps should be taken,

- Do not allow any product into or out of the area during the count or recount.
- Counts should be conducted from count sheet with the on hand quantities suppressed.
- Compare the inventory results with the current on-hand balance of each item.
- Recount any out-of-balance item.
- Run audit report for any out-of-balance item.
- Research the error, checking for orders picked but not invoiced, mispicks, etc.
- Make appropriate adjustments as errors causing variances are detected.
- The Distribution Center Manager should sign off on the count sheet that he has reviewed all exceptions and that variances have been explained.
- File DEA Form 106, on a timely basis, for any item that cannot be resolved.
- Create ARCOS transactions for any reportable items on DEA Form 106.

Retention of Inventory Records. The records must be retained for two years from the date the inventory was taken and must be available for DEA inspection at the registered location where the inventory was made. **(21 CFR 1304.04)**

Note: State record keeping requirements may be more than two years and should be maintained accordingly.

DEA REGISTRATION

Detecting Fraudulent Registration Numbers

A DEA registration number consists of a two-character prefix and a seven-character suffix which are determined as follows:

Prefix. 1st character is A or B for all practitioners, hospitals, pharmacies and teaching institutions; it is P or R for all other classes of registrants. M is used for mid-level practitioners (MLP). **(Refer to DEA Correspondence 8/25/93).** The 2nd character is the first letter of the registrant's last name if an individual, or the first letter in the first word of the name if a firm (Note, a "9" is inserted in this position if the firm's name begins with a number—e.g., "101 A Street, Inc.").

Suffix. The suffix contains seven numeric characters, the seventh of which is a check digit that is determined as follows:

Add the number of the 1st, 3rd and 5th characters to twice the sum of the 2nd, 4th and 6th characters; if the total is a single-digit number, that number is the check digit; if the total is a two-digit number, the digit in the ones column is the check digit and is inserted in the seventh position.

Checking Expiration Dates

A system to verify the renewal of registration number can be standardized by expiration date because all registrations with the same second character in the prefix expire on the same date. The expiration dates for these characters are:

January 31	M	July 31	B
February 28	S	August 31	C, E
March 31	L, P	September 30	F, G
April 30	Q, R, 9	October 31	H, N
May 31	U, V, W, X, Y, Z	November 30	I, T
June 30	A, D	December 31	J, K, O

Note: Practitioners, hospitals, pharmacies, and teaching institutions re-register every three years. All others register annually.

DEA Registration Verification

(21 CFR 1301.74(a))

The wholesaler is responsible for verifying that customers possess a valid, current DEA **Certificate of Registration (Exhibit J).** DEA will not verify routinely, and it is left to the wholesaler to develop a system. There are several methods the wholesaler may use.

Cardinal's policy and procedure requires that new accounts provide a photocopy of a current DEA registration prior to being allowed to purchase controlled substances. A copy of the account's state license should be obtained at the same time.

Registration expiration dates for existing accounts are monitored on a monthly basis. Those accounts whose registration is due to expire are contacted either by letter, telephone, or sales representative and are requested to provide an updated copy of their registration **(Exhibits K, L).** A copy of the state license should also be requested.

In addition, the computer system prohibits the purchase of controlled substances by any customer who does not have a DEA registration number loaded into the computer system or whose registration has expired. The system also limits the purchase of controlled substances to the schedules for which the customer is registered.

Cardinal purchases, on a quarterly basis, a tape from the DEA of all current registrations. This tape is run against each division's customer database. The **Quarterly DEA Exception Report (Exhibit N)** is a listing of all customers in a division's database whose DEA number or expiration date does not match the DEA database. Review and maintenance of this report must be done to assure sales of controlled substances are only made to current registrants of the DEA.

Questioned Registrations

Whenever there is reason to question a customer's registration (i.e., the number does not pass the check digit, there is a question whether the registration includes the schedule(s) ordered or a pharmacy has changed hands and the new owner is using the old DEA number), further inquiry should be made to ensure that the customer is properly registered. The local DEA office **will** check this type of situation. Calls to the local DEA office should be documented on a **Regulatory Agency Contact Form (Form #1).**

Delayed Registration Renewal Certificates

From time to time, computer delays at DEA cause customer renewals to be late, even though renewal applications were submitted in a timely fashion. When the customer tells the wholesaler that this has occurred, the wholesaler should contact the local DEA office to confirm this fact and to authorize continued shipments. If the authorization is made by telephone, the wholesaler should write down the confirmation, including the name of the authorizing DEA official, the date, and the details of the authorization. Document this on a **Regulatory Agency Contact Form. Refer to DEA Correspondence 9/7/93.**

Modification of DEA Registration

When a registrant moves to a new location, they must have the new location inspected by the DEA and obtain a new DEA registration with a corrected address. Many customers continue to use the old registration and expect that their controlled substance orders will be delivered to the new address. This is a violation of DEA regulations. Controlled substances can only be shipped to properly registered location and only to the address listed on the registration. **(21 CFR 1301.51)**

Transfer of Ownership

For a change of pharmacy ownership and continuing operation on a previous owner's DEA registration, the primary condition is that both the buyer and seller enter into a **Limited Power Of Attorney (Form #25)** that specifically sets forth the following:

- The seller agrees to allow the controlled substance activities of the pharmacy to be carried out under the seller's DEA registration;
- The seller agrees to allow the buyer to carry out the controlled substance activities of the pharmacy, including the ordering of controlled substances, as an agent of the seller;
- The seller acknowledges that, as the registrant, they will be held accountable for any violations of controlled substance laws which may occur; and
- The buyer agrees that the controlled substance activities of the pharmacy may be carried out under the seller's registration for no more than 45 days after the purchase date, which shall be recorded in the agreement.

Prior to selling product to the new owner, you should obtain a copy of the **Power Of Attorney** and file it with the copy of the previous owner's DEA registration certificate.

In addition, you must monitor the 45-day limit on controlled substance activity imposed as part of this policy. **Refer to DEA Correspondence 8/25/93.**

Termination of DEA Registration

(21 CFR 1301.52)

The closing of a facility requires that a DEA certificate of registration be terminated. At least 14 days prior to close and controlled substance transfer, submit a registered or certified letter, return receipt requested, to local DEA supervisor containing the following information:

- name, address, registration number of distribution center which is transferring the controlled substances and associated records and terminating the registration,
- name, address, registration number of distribution center to whom the controlled substances and associated records will be transferred,
- date of the controlled substance transfer and a description of the proposed transfer procedure,
- date and time of termination.

Contact state licensing agencies and follow their specific procedures for registration termination.

On the date of the transfer, a complete inventory of all controlled substances being transferred must be taken. A copy must be maintained with the records for each distribution center. The transfer must be documented as a purchase and sale. Purchase orders, 222's, invoices and receiving documents must be created.

The Corporate Compliance Department will arrange and supervise the transfer of all controlled substances.

Upon termination of the registration, submit to the regional DEA office by registered or certified mail, return receipt requested, a cover letter and the following:

- DEA Certificate of Registration,
- unused DEA Forms 222.

Chemical Registration

Any person or persons who distribute products covered by the Methampetamine Control Act (ephedrine, pseudoephedrine, phenylpropanolamine) must have either a controlled substance registration or a chemical registration. They do not have to possess both registrations. Registrations must be renewed annually.

A DEA chemical registration number consists of a six character prefix and a three character suffix which are determined as follows:

Prefix. The prefix contains six numeric characters. There is no check digit as in a controlled substance registration.

Suffix. The suffix contains three alpha characters. The first is the first letter in the registrants name. The second is a random letter and the third identifies the activity of the registrant as listed below.

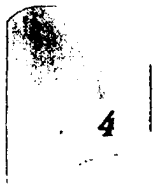
W - Manufacturer

Y - Distributor

V - Retail Distributor

X - Importer

Z - Exporter



MAINTENANCE OF RECORDS

The wholesaler is required to maintain on a current basis a complete and accurate record of every controlled substance received, distributed, or otherwise disposed of. Separate records are required for each registered location. Records of Schedule I (research drugs) and II drugs must be maintained separately (see section on Order Forms). All required records must be retained for two years. **(21 CFR 1304).**

Required Record Information

(21 CFR 1304.22 (b))

The following information is required for each controlled substance:

- Name of the substance.
- Each finished form (e.g., 10-mg. tablet or 10-mg. concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial).
- Number of commercial containers of each such finished form received from other persons, including the date of and number of containers in each receipt and the name, address, and registration number of the person from whom the containers were received.

  Note: Many wholesalers have been cited for failing to record the actual date of receipt on the document of transfer (e.g., invoice or packing slip) as well as the accurate name, address and registration number of the shipper.

- Number of commercial containers of each such finished form distributed to other persons, including the date of and number of containers in each distribution and the name, address and registration number of the person to whom the containers were distributed.

  Note: Wholesalers also have been cited for failing to record the actual shipping date as well as the accurate name, address, and registration number of the person to whom it was shipped. Ditto marks on DEA Form 222 are not acceptable for recording dates.

  Note: When providing backup service for another division, and shipping directly to the division's customer, your records must show that

customer as the recipient of the product. **Refer to DEA Correspondence 6/28/95.**

- Number of units or volume of finished forms and/or commercial containers distributed or disposed of in any other manner (e.g., by distribution as complimentary samples or by destruction) including the date and manner of distribution or disposal, the name, address and registration number of the person to whom distributed, and the quantity of the substance in finished form distributed or disposed of.

Automated Records Systems

Federal requirements can be met by either automated or manual records systems provided that the specific system contains all the necessary data elements. The wholesaler has the option of maintaining records for Schedule III through V transactions either separately or, if they are readily retrievable, with noncontrolled drug transactions. Ready retrievability requires that the records (whether an automated system, a manual system or a combination) clearly identify controlled drug transactions so that they can be extracted readily (i.e., identified by schedule symbol (C-III) or asterisk, redlined, on separate invoices for controlled drugs only, etc.).

Returns from Customers or to Manufacturers

Care must be taken to ensure that all the data elements are included on records for returns. These records must have the same information as that required on all receiving/shipping records including the name, address, and registration number of the customer/supplier, the name of the substance, each finished form, the number of units or volume and the number of containers; and the **actual** date the substance was received by the wholesaler or returned to the supplier. Schedule II returns must be made pursuant to a valid order form (see section on Order Forms).

Note: Wholesalers often fail to place the required information on return documents or to maintain Schedule III through V returns records in a readily retrievable manner.

Rules for Central Record Keeping

(21 CFR 1304.04)

Recognizing the trend toward the automation of business records in a central data center covering multiple locations, DEA allows financial and shipping records to be kept at a central location following written notification to the DEA special agent in charge of the field office covering the area where the registrant is located. The central records system may commence 14 days after the special agent in charge receives notification (sent in triplicate by certified or registered mail, return receipt requested). The notification must contain the name, address, and registration number of all locations to be included, the name and address of the exact location where the central records will be kept, a brief description of the records system and the records to be maintained centrally, and a statement agreeing

to make the records available at the registered location within two business days. If there is no response from DEA within 14 days after receipt by the special agent in charge, the wholesaler can proceed with the central records system. The wholesaler must, if DEA chooses, allow inspection at the central location in lieu of delivery to the registered location.

Exception: Inventories for all schedules of controlled drugs and Schedule II order forms must be kept at the registered location.

ARCOS participants wishing authorization to report from other than their registered location must obtain a **separate** central reporting identifier from the ARCOS Unit, P.O. Box 28293, Central Station, Washington, D.C. 20005, (202) 307-8600.

Microfilm/Microfiche Records

DEA does not consider copies of primary records an acceptable substitute for primary documents due to the opportunity for alteration when copying an original document. However, DEA will consider for approval on a case-by-case basis any system that simultaneously generates the copy and the original record. Approval of such a system requires DEA access to readers and printers as well as to the film. If a wholesaler microfilms/microfiches the originals for ease of handling, but retains the originals in backup storage for two years, this would satisfy DEA concerns as the originals could be made available for review as needed.

Drop Shipments of Controlled Substances

Wholesaler records of drop shipments are not required because these controlled substances are shipped directly from the supplier to the customer and never enter the wholesaler's possession. All such purchase orders and invoices must be clearly marked as drop shipments and should not be stored with records that document the actual receipt or distribution of controlled substances. Further, Schedule III narcotic substances which are drop-shipped are ARCOS reportable by the supplier on DEA Form 333.

Storage of Records

Care should be exercised to ensure that, for at least the two years they must be retained, all the wholesaler's controlled substances records are maintained in a secure and yet accessible manner. The controlled substance records are as follows:

- Receiving documentation
- Invoices and credit memos
- Narcotic Sales Report
- Narcotic Order Forms (DEA Form 222), brown and blue copies, and related records
- Monthly ARCOS Report
- ARCOS Edit Error Report and submission

- Count Sheets from Periodic Inventories
- Suspicious Order Analysis, or Excessive Purchase Report
- DEA Form 106
- DEA Form 41
- Return Receipt Requested forms for any mailings
- Debit Memos for Returns to Vendors
- Year-End ARCOS Inventory
- Biennial Inventory

DEA requires that records be maintained for two years. Record retention requirements for individual states may vary. Additional records may be maintained as required by division policy.

Shipping Errors

Shipping errors must be documented as any normal transfer of controlled substances would be and as mandated by DEA record keeping and reporting requirements. In other words, any transfer of controlled substances, regardless if shipped in error, must be appropriately documented with 222s, invoices, credit memos, and ARCOS reporting as applicable. The swapping of the right product for the wrong product is inappropriate. Each distribution and return must be documented as a separate independent transaction. These requirements apply to intra-company as well as customer shipments. Several examples of shipping error scenarios and the corresponding corrective actions are included as Exhibit Q.

Brokerage Operations

Some Cardinal Distribution facilities have brokerage business operating within their distribution center. The brokerage business operates on the division's DEA registration number, therefore the division is ultimately responsible for compliance with DEA regulatory requirements as they apply to brokerage operations. Key compliance issues related to the division/brokerage operating relationship are as follows:

- Brokerage personnel must coordinate with division personnel to ensure they are following all division procedures related to the receipt, distribution, storage, inventory, etc. of controlled substances.
- All transaction records and reports for brokerage purchases, sales and other dispositions of controlled substances must be included in the division's records. On the distrack system this is accomplished through a month end records transfer from the brokerage system to the division system. HP divisions maintain hard copy records and adds ARCOS records through a manual process.
- Records for controlled substance transactions between brokerage and the division are not required records since brokerage operates on the division's DEA registration. These records must be deleted from the brokerage and division record keeping systems.

- Brokerage controlled substance inventory must be stored in the cage and vault, but is maintained separately from the division's inventory and is identified as brokerage inventory.
- Although brokerage inventory is maintained separately, it must be included in all inventories conducted by the division.
- The division must be licensed, as required, in those states into which they distribute to brokerage customers.
- The division must verify and maintain a copy of all brokerage customer DEA registrations and state licenses.

A more detailed description of brokerage operations is contained in the **Brokerage Warehouse Operations Procedures Manual** which should be available to you from brokerage personnel located in your division.

ORDER FORMS

(21 CFR 1305)

All transactions of Schedule I and II substances must be made on federal order forms - **DEA Form 222 (Exhibit O).** Any exceptions to this requirement must be approved by DEA on a case-by-case basis. Purchases from vendors and returns from customers are executed on order forms issued by Cardinal Health. Sales to customers are executed on order forms issued by the customer.

Obtaining and Executing Order Forms

Only persons registered to handle Schedule I and/or II substances may obtain order forms. Order forms may be executed only on behalf of the registrant named on the order form provided that the registrant **currently** is registered to handle the scheduled substances ordered.

When blanks are received from the DEA, the order form numbers should be logged on the **DEA Narcotic Blank Log (Form #4),** and kept in the vault for safekeeping, pending use.

Separate Records Requirement

DEA has taken the position that order forms are the primary record of Schedule II transactions and, therefore, that the maintenance of order forms in a separate file satisfies the requirement that records of Schedule II transactions be maintained separately. Secondary records (e.g., invoices accompanying order forms) are not required to be maintained separately.

Purchases and Returns of Schedule I and II substances

Procedure for Executing Order Forms

(21 CFR 1305.06)

- The purchaser simultaneously prepares and executes order forms in triplicate by means of interleaved carbon sheets which are part of the DEA Form 222. Order forms are prepared by use of a typewriter, pen or indelible pencil. A wholesaler may consider rejecting any Form 222 completed in pencil, indelible or not, as the identification of indelible over regular lead is tenuous at best.

- Only one item is entered on each numbered line. There are 10 lines on each order form. Some registrants still are using the old five-line order forms, which are valid.